UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

TEVA PHARMACEUTICALS INTERNATIONAL GMBH and TEVA PHARMACEUTICALS USA, INC.,	*	Civil Action No. 1:17-cv-12087-ADB
Plaintiffs,	*	*Related Case:*
v.	*	Civil Action No. 1:18-cv-10242-ADB
ELI LILLY AND COMPANY,	*	
Defendant.	*	

MEMORANDUM AND ORDER ON MOTIONS TO DISMISS

BURROUGHS, D.J.

Plaintiffs Teva Pharmaceuticals International GmbH and Teva Pharmaceuticals USA, Inc. (collectively, "Teva") filed two related declaratory judgment actions against Defendant Eli Lilly and Company ("Lilly"), which are both before this Court. Teva Pharm. Int'l GmbH v. Eli Lilly & Co., No. 17-cv-12087-ADB ("Teva I"); Teva Pharma. Int'l GmbH v. Eli Lilly & Co., 18-cv-10242-ADB ("Teva II"). Teva alleges that Lilly's commercial manufacture, importation, offers to sell, and sales of its biologic product galcanezumab would, upon receiving FDA approval, directly infringe, or would induce or contribute to the infringement of nine patents assigned to Teva. Lilly moved to dismiss both actions pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). [Teva I, Dkt. No. 23; Teva II, Dkt. No. 13]. This Memorandum and Order addresses both pending motions and, for the reasons set forth below, the motions to dismiss are GRANTED.

I. BACKGROUND

A. Pleadings and Procedural History

Plaintiff Teva Pharmaceuticals International GmbH is a Swiss limited liability company with a principal place of business in Jona, Switzerland. [Teva I, Dkt. 21 ¶ 7]. Plaintiff Teva Pharmaceuticals USA, Inc. is a Delaware corporation with a principal place of business in North Wales, Pennsylvania. [Id. ¶ 8].

Labrys Biologics, Inc. ("Labrys"), a corporate affiliate of Teva, developed a biologic product with an active ingredient called fremanezumab. [Id. ¶ 3]. A biologic is a type of drug derived from natural, biological sources such as plants, animals, or microorganisms. Sandoz Inc. v. Amgen Inc., 137 S. Ct. 1664, 1669 (2017). Fremanezumab is an antibody that targets a molecule called calcitonin gene-related peptide, or CGRP, and that has been shown to prevent or reduce the incidence of migraine headaches. [Teva I, Dkt. 21 ¶ 3]. On October 16, 2017, Teva Branded Pharmaceutical Products R&D, Inc. submitted a Biologics License Application ("BLA") to the Food and Drug Administration ("FDA") seeking approval to market fremanezumab for the treatment of migraine headaches. [Id. ¶ 4].

Teva is the assignee of several patents that are relevant to this dispute. On November 19, 2013, the United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 8,586,045, entitled "Methods of Using Anti-CGRP Antagonist Antibodies." On December 3, 2013, the USPTO issued U.S. Patent No. 8,597,649, entitled "Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide and Methods Using Same." On February 23, 2016, the USPTO issued U.S. Patent No. 9,266,951, entitled "Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide and Methods Using Same." On May 17, 2016, the USPTO issued U.S. Patent No. 9,340,614, entitled "Antagonist Antibodies Directed Against Calcitonin

Gene-Related Peptide and Methods Using Same." On May 24, 2016, the USPTO issued U.S. Patent No. 9,346,881, entitled "Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide and Methods Using Same." On February 6, 2018, the USPTO issued U.S. Patent No. 9,884,907, entitled "Methods for Treating Headache Using Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide." On February 6, 2018, the USPTO issued U.S. Patent No. 9,884,908, entitled "Methods for Treating Headache Using Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide." On February 13, 2018, the USPTO issued U.S. Patent No. 9,890,210, entitled "Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide." On February 13, 2018, the USPTO issued U.S. Patent No. and 9,890,211, entitled "Antagonist Antibodies Directed Against Calcitonin Gene-Related Peptide." [Teva I, Dkt. No. 21 ¶ 4; Teva II, Dkt. No. 10 ¶ 4] (collectively, the "Teva Patents").

Defendant Lilly is an Indiana corporation with a principal place of business in Indianapolis, Indiana. [Teva I, Dkt. No. 21 ¶ 9]. Lilly developed a biologic product with an active ingredient called galcanezumab, which targets the same CGRP molecule that fremanezumab targets, and similarly has been shown to prevent or reduce the incidence of migraine headaches. [Id. ¶ 5; Teva I, Dkt. No. 21-2 at 20]. On October 24, 2017, eight days after Teva submitted its BLA, Lilly submitted a BLA to the FDA seeking approval to market galcanezumab for the treatment of migraine headaches. [Teva I, Dkt. No. 21 ¶ 5].

That same day, Teva filed its first declaratory judgment action against Lilly, alleging that Lilly's commercial manufacture, importation, offers to sell, and sales of galcanezumab would, upon receiving FDA approval, directly infringe or would induce or contribute to the infringement of five of the Teva Patents, U.S. Patent Nos. 8,586,045; 8,597,649; 9,266,951; 9,340,614; and 9,346,881. [Teva I, Dkt. No. 1]. On December 15, 2017, Lilly moved to dismiss the declaratory

judgment action pursuant to Federal Rules of Civil Procedure 12(b)(1), 12(b)(2), and 12(b)(3) or, in the alternative, to partially dismiss the action pursuant to Federal Rule of Civil Procedure 12(b)(6) or transfer the action to the Southern District of Indiana pursuant to 28 U.S.C. § 1404(a). [Teva I, Dkt. No. 16]. In response to this motion, on January 17, 2018, Teva filed an amended complaint. [Teva I, Dkt. No. 21]. On January 30, 2018, Lilly again moved to dismiss the amended complaint in Teva's first declaratory judgment action pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). [Teva I, Dkt. No. 23].

On February 6, 2018, Teva filed a second declaratory judgment action against Lilly, alleging substantially similar declaratory judgment claims, including that Lilly's commercial manufacture, importation, offers to sell, and sales of galcanezumab would, upon receiving FDA approval, directly infringe or would induce or contribute to the infringement of those patents, in connection with two of the Teva Patents, U.S. Patent Nos. 9,884,907 and 9,884,908. [Teva II, Dkt. No. 1]. On February 13, 2018, Teva filed an amended complaint, adding declaratory judgment claims in connection with two other Teva Patents, U.S. Patent Nos. 9,890,210 and 9,890,211. [Teva II, Dkt. No. 10] (together, with Teva I, Dkt. No. 21, the "Amended Complaints"). On February 28, 2018, Lilly moved to dismiss the first amended complaint in Teva's second declaratory judgment action pursuant to Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). [Teva II, Dkt. No. 13].

On September 14, 2018, Teva's BLA was approved by the FDA. Lilly's BLA is currently under review by the FDA.

B. Statutory Framework

To resolve these motions, it is necessary to recount briefly the federal statutory framework governing the marketing of new drugs, generic drugs, new biologics, and follow-on

biosimilars (*i.e.*, a biological product that is "highly similar" to a reference biologic) and the Safe Harbor provision of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (the "Hatch-Waxman Act").

Before a pioneering drug manufacturer can market a new drug, it must obtain FDA approval by submitting a New Drug Application ("NDA"). See 21 U.S.C. § 355(a), (b). An NDA is the result of extensive testing and must include safety information, efficacy information, and composition data. See 21 U.S.C. § 355(b). As part of an NDA, the drug manufacturer must notify the FDA of all patents covering its drug or the methods of using the drug "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." See 21 U.S.C. § 355(b)(1), (c)(2). The FDA lists all such patents in a publication titled the "Approved Drug Products With Therapeutic Equivalence Evaluations," known as the "Orange Book." See Bayer Schering Pharma AG v. Lupin, Ltd., 676 F.3d 1316, 1318 (Fed. Cir. 2012).

Before a drug manufacturer can market a generic drug, it must obtain FDA approval by submitting an Abbreviated New Drug Application ("ANDA"). See 21 U.S.C. § 355(j). To facilitate the development of generic versions of pioneer drugs, the Hatch-Waxman Act expedited the FDA approval process for generic drugs and "substantially shorten[ed] the time and effort needed to obtain marketing approval." Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990); see 21 U.S.C. § 355(j). Under the ANDA process, a generic drug manufacturer must show that its generic drug and the approved drug share the same active ingredients and are bioequivalent, but it may rely on the safety and efficacy studies of the approved drug. See 21 U.S.C. § 355(j)(2)(A)(ii), (iv).

In addition to creating the expedited ANDA approval process, to allow consumers accelerated access to generic versions of approved drugs, the Hatch-Waxman Act also established a patent dispute resolution framework that "enable[s] a court to promptly resolve any dispute concerning infringement and validity" by allowing infringement suits to begin based on the filing of an ANDA, prior to FDA approval and the marketing of the generic drug. Allergan, Inc. v. Alcon Labs., Inc., 324 F.3d 1322, 1330 (Fed. Cir. 2003) (citation omitted). If a generic drug manufacturer seeks to market a generic version of an approved drug before the Orange Book-listed patents covering that drug expire, it must file a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification"). Under the Hatch-Waxman Act, the mere act of filing a Paragraph IV certification constitutes an "act of infringement" that a patentee may litigate. See 35 U.S.C. § 271(e)(2) ("It shall be an act of infringement" to submit an ANDA "if the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent."). As the Federal Circuit has explained, "§ 271(e)(2) is designed to create an *artificial* act of infringement for purposes of establishing jurisdiction in the federal courts." Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1351 (Fed. Cir. 2004).

Before a pioneering biologic manufacturer can market a new biologic, it must obtain FDA approval by submitting a BLA. See 42 U.S.C. § 262(a). The new BLA must provide clinical data to demonstrate, *inter alia*, that the biologic is safe, pure, and potent. Id. § 262(a)(2)(C)(i)(I). For biologics, there is no equivalent to the Orange Book that lists each patent that claims the drug or a method of using the drug that is the subject of the BLA.

Before a biologic manufacturer can market a follow-on biosimilar, it must obtain FDA approval by submitting an Abbreviated Biologics License Application ("aBLA"). "[B]orrowing

from (though not copying) the Hatch-Waxman Act's process for use of an [ANDA], rather than a full [NDA], to obtain approval of generic versions of previously approved drugs," the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), Pub. L. No. 111-148, §§ 7001–7003, 124 Stat. 119, 804–21 (2010), established an FDA approval process for biosimilars that is more abbreviated than the BLA process. See Sandoz Inc. v. Amgen Inc., 773 F.3d 1274, 1276 (Fed. Cir. 2014); 42 U.S.C. § 262(k). An applicant filing an aBLA must demonstrate that its product is "biosimilar" to or "interchangeable" with a previously approved biologic, but it may rely on "publicly-available information regarding the [FDA]'s previous determination that the reference biologic is safe, pure, and potent." Id. § 262(k)(2)–(5); see also id. § 262(i). Similar to the Hatch-Waxman Act, "[t]he BPCIA contains a dispute resolution mechanism in order to ensure that patent disputes are resolved prior to the end of the reference product's exclusivity period" to "enabl[e] biosimilar products to enter the market promptly upon the expiration of exclusivity." Celltrion Healthcare Co. v. Kennedy Tr. for Rheumatology Research, No. 14-cv-2256-PAC, 2014 WL 6765996, at *2 (S.D.N.Y. Dec. 1, 2014); see 35 U.S.C. § 271(e)(2)(C), (e)(4), (e)(6); Sandoz, 137 S. Ct. at 1670 ("The BPCIA facilitates litigation during the period preceding FDA approval so that the parties do not have to wait until commercial marketing to resolve their patent disputes" and "enables the parties to bring infringement actions . . . even if the applicant has not yet committed an act that would traditionally constitute patent infringement.").

The Hatch-Waxman Act also established a Safe Harbor provision that provides a statutory exception to patent infringement liability. A U.S. patent grants a patentee the right to "exclude others from making, using, offering for sale, or selling" the patented invention in the United States. 35 U.S.C. § 154(a)(1). Thus, ordinarily, anyone who makes, uses, offers to sell, or sells any patented invention in the United States without permission from the patentee

infringes the patent. See 35 U.S.C. § 271(a). The Safe Harbor provision creates an exception to this general rule and permits anyone to engage in what would constitute infringing activities before the patent expires so long as those activities are "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." 35 U.S.C. § 271(e)(1). Although Congress enacted the Safe Harbor in the context of the ANDA approval process, the provision is not so limited, and applies to, *inter alia*, the development and submission of new drugs, new biologics, follow-on biosimilars, and generic drugs. See Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 205–08 (2005); Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1356–57 (Fed. Cir. 2012) (The Safe Harbor "'exempt[s] from infringement *all* uses of patented compounds "reasonably related" to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs.'").

Thus, as relevant here, the statutory framework governing the development, submission, and marketing of new drugs, generic drugs, new biologics, and follow-on biosimilars is asymmetrical. While Congress provided that pioneer and follow-on drug and biologic manufacturers all benefit from the Safe Harbor provision's statutory exemption to patent infringement liability, Congress has facilitated litigation during the period preceding FDA approval, prior to commercial marketing, only in connection with ANDA and aBLA submissions, and not upon the mere submission of an NDA or BLA.

II. DISCUSSION

A. Standard of Review

Defendant moves pursuant to Federal Rule of Civil Procedure 12(b)(1) to dismiss all of Plaintiffs' claims for lack of subject matter jurisdiction and pursuant to Federal Rule of Civil Procedure 12(b)(6) to dismiss Plaintiffs' claims for willful infringement for failure to state a claim.

1. Federal Rule of Civil Procedure 12(b)(1)

A 12(b)(1) motion to dismiss for lack of subject matter jurisdiction may raise either a facial or factual challenge. See Torres-Negrón v. J & N Records, LLC, 504 F.3d 151, 162 (1st Cir. 2007). "While a party raising a facial challenge accepts the truth of the non-moving party's allegations and questions the sufficiency of those allegations, a party raising a factual challenge questions the accuracy of the non-moving party's jurisdictional facts." Piro v. Exergen Corp., No. 15-CV-11834-DJC, 2016 WL 1255630, at *1 (D. Mass. Mar. 29, 2016) (citing Valentin v. Hosp. Bella Vista, 254 F.3d 358, 363 (1st Cir. 2001)). Here, Lilly raises a factual challenge. [Teva II, Dkt. No. 14 at 6 n.1.]

In resolving a factual challenge to subject matter jurisdiction, the court engages in a two-part inquiry. "First, the court must determine whether the relevant facts, which would determine the court's jurisdiction, also implicate elements of the plaintiff's cause of action." Torres-Negrón, 504 F.3d at 163. "Where the jurisdictional issue and substantive claims are so intertwined [that] the resolution of the jurisdictional question is dependent on factual issues going to the merits, the district court should employ the standard applicable to a motion for summary judgment." Id. (quoting Autery v. United States, 424 F.3d 944, 956 (9th Cir. 2005) (alterations omitted). "Thus, where the relevant facts are dispositive of both the 12(b)(1) motion and portions of the merits, the trial court should grant the motion to dismiss only if the material

jurisdictional facts are not in dispute and the moving party is entitled to prevail as a matter of law." Id. (citations and quotation marks omitted). "If the plaintiff presents sufficient evidence to create a genuine dispute of material (jurisdictional) facts, then the case proceeds to trial, so that the factfinder can determine the facts, and the jurisdictional dispute will be reevaluated at that point." Id.

Second, where the facts relevant to the jurisdictional inquiry "are not intertwined with the merits of the plaintiff's claim, the trial court may proceed as it never could under 12(b)(6)" and "weigh the evidence and satisfy itself as to the existence of its power to hear the case." Id. (citations and quotation marks omitted). Here, as described below, Defendant makes a factual challenge based on whether an "actual controversy" exists under the Declaratory Judgment Act. Resolution of this question is not dependent on factual matters going to the merits of Plaintiffs' patent infringement claims. As such, the jurisdictional issue and substantive claims are not intertwined, and in conducting its jurisdictional inquiry, this Court "enjoys broad authority to order discovery, consider extrinsic evidence, and hold evidentiary hearings in order to determine its own jurisdiction." Valentin, 254 F.3d at 363. "[T]he plaintiff's jurisdictional averments are entitled to no presumptive weight" and "the court must address the merits of the jurisdictional claim by resolving the factual disputes between the parties." Id. at 363–64 ("[W]hen a factbound jurisdictional question looms, a court must be allowed considerable leeway in weighing the proof, drawing reasonable inferences, and satisfying itself that subject-matter jurisdiction has attached.").

2. Federal Rule of Civil Procedure 12(b)(6)

To withstand a motion to dismiss under Federal Rule of Civil Prodecure 12(b)(6), a complaint must allege a claim for relief that is "plausible on its face." Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007). Assessing the plausibility of a claim is a two-step process:

> First, the court must sift through the averments in the complaint, separating conclusory legal allegations (which may be disregarded) from allegations of fact (which must be credited). Second, the court must consider whether the winnowed residue of factual allegations gives rise to a plausible claim to relief.

Rodriguez-Reyes v. Molina-Rodriguez, 711 F.3d 49, 53 (1st Cir. 2013) (citation omitted). Along with all well-pleaded facts, the Court must draw all reasonable inferences from a complaint in favor of the plaintiff. Frappier v. Countrywide Home Loans, Inc., 750 F.3d 91, 96 (1st Cir. 2014). "If the factual allegations in the complaint are too meager, vague, or conclusory to remove the possibility of relief from the realm of mere conjecture, the complaint is open to dismissal." Rodríguez-Reyes, 711 F.3d at 53 (quoting SEC v. Tambone, 597 F.3d 436, 442 (1st Cir. 2010) (en banc)).

"When a court is confronted with motions to dismiss under both Rules 12(b)(1) and 12(b)(6), it ordinarily ought to decide the former before broaching the latter," because "if the court lacks subject matter jurisdiction, assessment of the merits becomes a matter of purely academic interest." Deniz v. Municipality of Guaynabo, 285 F.3d 142, 149–50 (1st Cir. 2002). The Court will so proceed.

B. Declaratory Judgment Act

The Declaratory Judgment Act authorizes courts to "declare the rights and other legal relations of any interested party seeking such declaration" when there is a "case of actual controversy." 28 U.S.C. § 2201(a). "The Act creates a remedy, not an independent source of subject-matter jurisdiction." Sandoz, 773 F.3d at 1277. Rather, "the phrase 'case of actual controversy' in the Act refers to the type of 'Cases' and 'Controversies' that are justiciable under Article III." MedImmune, Inc. v. Genentech, Inc., 549 U.S. 118, 127 (2007) (quoting Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 240 (1937)). "The party seeking to establish declaratory judgment jurisdiction bears the burden of demonstrating that an Article III case or controversy

exists at the time the claim for declaratory relief is filed." Matthews Int'l Corp. v. Biosafe Eng'g, LLC, 695 F.3d 1322, 1328 (Fed. Cir. 2012).

To determine whether an "actual controversy" is present, the court must evaluate "whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant" the issuance of a declaratory judgment. MedImmune, 549 U.S. at 127 (quoting Md. Cas. Co. v. Pac. Coal & Oil Co., 312 U.S. 270, 273, (1941)). "The inquiry, focused on the combination of immediacy and reality, involves no bright-line test." Sandoz, 773 F.3d at 1277. Instead, "the analysis must be calibrated to the particular facts of each case," because "'[t]he difference between an abstract question and a "controversy" contemplated by the Declaratory Judgment Act is necessarily one of degree, and it would be difficult, if it would be possible, to fashion a precise test for determining in every case whether there is such a controversy.'" Cat Tech. LLC v. TubeMaster, Inc., 528 F.3d 871, 879 (Fed. Cir. 2008) (quoting Md. Cas. Co., 312 U.S. at 273).

Courts assess "immediacy" by evaluating "how far in the future the potential infringement is, whether the passage of time might eliminate or change any dispute, and how much if any harm . . . an adjudication might redress." Sandoz, 773 F.3d at 1278 (citing Matthews, 695 F.3d at 1329–30 (collecting cases)). Courts assess "reality" by considering whether the design of the product in question is "'substantially fixed' as opposed to 'fluid and indeterminate' at the time declaratory relief is sought." Cat Tech., 528 F.3d at 882 (quoting Sierra Applied Scis., Inc. v. Advanced Energy Indus., Inc., 363 F.3d 1361, 1379 (Fed. Cir. 2004). The Federal Circuit has instructed that ripeness principles "serve as helpful guides" in assessing immediacy and reality and "reinforce the importance of contingency in the analysis." Sandoz,

773 F.3d at 1278 (citation, quotation marks, and alterations omitted); see also Texas v. United States, 523 U.S. 296, 300 (1998) ("A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all." (internal quotation marks omitted)).

Even when an "actual controversy" exists, the Declaratory Judgment Act "confer[s] on federal courts unique and substantial discretion in deciding whether to declare the rights of litigants." Wilton v. Seven Falls Co., 515 U.S. 277, 286 (1995) ("On its face, the statute provides that a court '*may* declare the rights and other legal relations of any interested party seeking such declaration,' 28 U.S.C. § 2201(a)."); see also Kiely v. Canty, 102 F. Supp. 3d 359, 366 (D. Mass. 2015) ("Where a complaint solely seeks declaratory relief, the Court 'has substantial discretion to decline to enter a declaratory judgment.'" (quoting CE Design, Ltd. v. Amer. Econ. Ins. Co., 947 F. Supp. 2d 151, 158 (D. Mass. 2012))). "In the declaratory judgment context, the normal principle that federal courts should adjudicate claims within their jurisdiction yields to considerations of practicality and wise judicial administration." Wilton, 515 U.S. at 288 (citations omitted).

1. Actual Controversy

Plaintiffs argue that an "actual controversy" under the Declaratory Judgment Act exists because the Amended Complaints allege imminent FDA approval and actual threats of future infringement. [Teva I, Dkt. No. 36 at 1]. For the reasons set forth below, the Court finds that Plaintiffs' allegations are insufficient to set forth a justiciable controversy.

Specifically, Plaintiffs argue that they have alleged a controversy of sufficient immediacy and reality to establish jurisdiction because Defendant has made substantial investments in preparing and submitting a BLA for galcanezumab in order to secure prompt FDA approval.

[Teva I, Dkt. No. 26 at 4, 10; Teva II, Dkt. No. 17 at 4, 10]. Plaintiffs contend that the expected date of FDA approval for galcanezumab is October 2018 based on Defendant's public disclosures and the timeframes for FDA approval decisions as set forth in the Prescription Drug User Fees Act ("PDUFA"). [Teva I, Dkt. No. 26 at 1, 3, 5, 10; Teva I, Dkt. No. 36 at 6; Teva II, Dkt. No. 17 at 1, 3, 5, 10]. Plaintiffs also contend that FDA approval is imminent given Defendant's extensive experience working with the FDA to secure approval of its drugs. [Teva I, Dkt. No. 26 at 2, 11; Teva II, Dkt. No. 17 at 2, 11]. Further, Plaintiffs claim that Defendant has taken steps both to prime the market for galcanezumab by initiating a social-media campaign and other advertising measures [Teva I, Dkt. No. 26 at 1, 11; Teva I, Dkt. No. 36 at 6; Teva II, Dkt. No. 17 at 1, 10], and to execute its commercial launch of galcanezumab by hiring sales representatives. [Teva I, Dkt. No. 26 at 1–2, 11; Teva II, Dkt. No. 17 at 1, 10].

In response, Defendant argues that the actions it has taken in connection with its galcanezumab BLA submission are protected by the Safe Harbor provision of the Hatch-Waxman Act. [Teva I, Dkt. No. 24 at 1, 12; Teva II, Dkt. No. 14 at 1, 16]. Defendant contends that any future infringement is too speculative to establish jurisdiction because FDA review is a lengthy and uncertain process, and FDA timelines under the PDUFA do not guarantee when or whether approval will occur. [Teva I, Dkt. No. 24 at 2, 12; Teva II, Dkt. No. 14 at 2, 12]. According to Defendant, approval times for neurology therapeutics, like galcanezumab, rank among the slowest, and only 45% are approved on their first review. [Teva I, Dkt. No. 24 at 12; Teva II, Dkt. No. 14 at 14]. Defendant further asserts that the social-media account and website that Plaintiffs allege constitute market preparations do not establish immediacy because they do not promote galcanezumab and that, unless and until galcanezumab receives FDA approval, the

newly hired sales representatives will be responsible for marketing already-approved products. [Teva I, Dkt. No. 24 at 13; Teva II, Dkt. No. 14 at 14].

The Court finds that whether and when the FDA will approve galcanezumab is too uncertain to support a finding that there is a substantial controversy of sufficient immediacy and reality to warrant the issuance of a declaratory judgment in these cases. Plaintiffs do not dispute that all actions that Defendant has taken to prepare and submit its BLA for galcanezumab fall within the Safe Harbor of the Hatch-Waxman Act. Defendant has not, as the Amended Complaints allege, publicly expressed confidence that FDA approval of galcanezumab is imminent. At most, Defendant has stated that it expects regulatory action on galcanezumab in 2018 (which could result in rejection),[1] and that a 2018 launch of galcanezumab is possible.[2] [See Teva I, Dkt. No. 21-2 at 19–20 ("For galcanezumab, there's a *potential* for launch for both cluster and migraine headache prevention in 2018." (emphasis added)); Teva I, Dkt. No. 21-3 at 6 (galcanezumab "product launch[] *possible*" in 2018 (emphasis added))]; contra LifeScan Scotland, Ltd. v. Shasta Techs., LLC, No. 5:11-CV-04494-EJD, 2012 WL 2979028, at *6 (N.D. Cal. July 19, 2012) (finding declaratory judgment jurisdiction where defendant disclosed to the SEC that "[the date of FDA approval] will be imminent" and that defendant "believed it would introduce the [product] last year and that all hurdles to FDA approval have been overcome").

[1] See Teva I, Dkt. No. 21-7 (defining "review and act on" under the PDUFA as "the issuance of a complete action letter after the complete review of a filed complete application. The action letter, if it is not an approval, will set forth in detail the specific deficiencies and, where appropriate, the actions necessary to place the application in condition for approval.").

[2] Plaintiffs similarly assert that FDA approval of galcanezumab is imminent because Defendant has factored the launch of galcanezumab into its long-term revenue growth projections. [Teva I, Dkt. No. 26 at 5; Teva I, Dkt. No. 21 ¶ 17]. Plaintiffs omit, however, that Defendant has factored the launch of galcanezumab into its long-term revenue growth projections on a "probabilized basis," which may incorporate the probability that FDA action is delayed or that the drug is ultimately not approved. [Teva I, Dkt. No. 21-5 at 21].

The parties spend a great amount of time arguing about the likely timeframe of FDA action, but "[t]he immediacy requirement is not concerned in the abstract with the amount of time that will occur between the filing of the declaratory judgment action and the liability-creating event." Sandoz, 773 F.3d at 1277–78. Instead, the immediacy requirement is concerned with "uncertainty," see id., and even assuming that Plaintiffs' estimate for FDA action were correct, Plaintiffs' allegation that the FDA will approve galcanezumab is "speculative at best." Juno Therapeutics, Inc. v. Kite Pharma, Inc., No. 16-cv-1243-RGA, 2017 WL 2559735, at *3 (D. Del. June 13, 2017) (dismissing declaratory judgment action filed when BLA was pending for lack of jurisdiction and finding that plaintiffs failed to allege sufficient facts "from which [the court] could conclude that FDA approval of Defendant's BLA [was] imminent or even certain"); see also Clarus Therapeutics, Inc. v. Lipocine, Inc., No. 15-cv-1004-RGA-MPT, 2016 WL 5868065, at *3 (D. Del. Oct. 6, 2016) (dismissing declaratory judgment action when NDA was pending for lack of jurisdiction and finding that "when, and even whether, the FDA will approve Defendant's NDA [was] still speculative" and "[n]o amount of market research or hiring of sales personnel can alter the speculative nature of any future infringement"); Reckitt Benckiser Pharm., Inc. v. Biodelivery Scis. Int'l, Inc., No. 13-cv-760-BO, 2014 WL 2119822, at *3 (E.D.N.C. May 21, 2014) (dismissing declaratory judgment action when NDA was pending for lack of jurisdiction and finding that "[a]lthough plaintiffs allege that defendant has announced its intent to market [drug] once it obtains FDA approval, any actual future alleged infringement of plaintiffs' patent 'depends on two contingent future events: FDA approval of defendant's NDA, and defendant's decision to market [drug] pursuant to that NDA'" and "[a]t least until the NDA is approved . . . the controversy is not sufficiently immediate" (quoting Eisai Co. v. Mut. Pharm. Co., 06-cv-3613-HAA, 2007 WL 4556958 (D.N.J. Dec. 20, 2007) (alterations omitted)).

Plaintiffs rely heavily on Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562 (Fed. Cir. 1997) to argue that their allegations are sufficient to establish an "actual controversy." In Glaxo, the defendant submitted an ANDA seeking approval to make and sell a generic version of the patentee's drug and filed a Paragraph IV certification notifying the patentee that it intended to market the generic drug prior to patent expiration. 110 F.3d at 1564. The patentee brought an "artificial" infringement claim under Section 271(e)(2) and a declaratory judgment claim based on a "method of making" patent, which the patentee could not assert under Section 271(e)(2). Id.; see also 35 U.S.C. § 271(e)(2) (authorizing claims only directed to drugs or methods of using drug). The Federal Circuit affirmed jurisdiction over the declaratory judgment action because, *inter alia*, the defendant had "submitted an ANDA accompanied by data sufficient to make FDA approval imminent." Id. at 1571.

The Court finds Glaxo inapposite for two reasons. First, "[t]here is a significant difference, both in terms of timing and certainty, between the ANDA approval process and the process of obtaining approval of a BLA" or an NDA. Juno Therapeutics, 2017 WL 2559735, at *2; see also Glaxo Grp. Ltd. v. Apotex, Inc., 130 F. Supp. 2d 1006, 1007 n.2 (N.D. Ill. 2001). As described supra at 5, an ANDA applicant is not required to demonstrate the generic drug's safety or efficacy because it can rely on the approved drug's clinical studies. The ANDA applicant need only show that its generic drug and the approved drug share the same active ingredients and are bioequivalent. A BLA applicant, on the other hand, must prove that its biologic is safe, pure, and potent, and an NDA applicant must prove that its drug is safe and effective. See supra at 6. Between 2006 and 2015, 19% of Neurology BLA and NDA submissions were ultimately not approved by the FDA. See Teva I, Dkt. No. 25-5 at 12. A declaratory judgment claim "is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or

indeed may not occur at all." Texas v. United States, 523 U.S. at 300 (internal quotation marks omitted).

In addition, the Federal Circuit's decisions finding declaratory judgment jurisdiction in the ANDA context—including Glaxo—reflect the fact that the Hatch-Waxman Act contemplates litigation of ANDA submissions before FDA approval. See Apotex, Inc. v. Daiichi Sankyo, Inc., 781 F.3d 1356, 1364–65 (Fed. Cir. 2015). "The Supreme Court and [the Federal Circuit] have recognized the potential significance of congressional action in 'articulat[ing] chains of causation that will give rise to a case or controversy where none existed before.'" Id. at 1365 (quoting Massachusetts v. EPA, 549 U.S. 497, 516 (2007)). "By deeming certain series of links from conduct to harm or from judgment to alleviation of harm not to be unduly speculative, Congress may 'effectively creat[e] justiciability that attenuation concerns would otherwise preclude.'" Apotex, 781 F.3d at 1365 (quoting Sandoz, 773 F.3d at 1281). This is precisely what Congress did when it deemed filing an ANDA with a Paragraph IV certification an act of infringement under the Hatch-Waxman Act. 35 U.S.C. § 271(e)(2); see Apotex, 781 F.3d at 1365 ("Congress, in [the Hatch-Waxman Act], defined an 'artificial act of infringement" . . . that allows litigation to take place well before any product is actually placed on the market and before any FDA regulatory approval."). Here, Plaintiffs cannot invoke any statutory relaxation of otherwise-applicable immediacy and reality requirements where no federal statute similarly contemplates litigation upon the filing of a BLA.[3]

[3] Plaintiffs also rely on several other cases in the ANDA context to argue that an "actual controversy" exists. [See Teva I, Dkt. No. 26 at 10 n.6 (citing Cephalon, Inc. v. Sandoz, Inc., No. 11-cv-821-SLR, 2012 WL 682045 (D. Del. Mar. 1, 2012); Takeda Chem. Indus., Ltd. v. Watson Pharms., Inc., 329 F. Supp. 2d 394 (S.D.N.Y. 2004); Glaxo Grp. Ltd. v. Apotex, Inc., 130 F. Supp. 2d 1006 (N.D. Ill. 2001))]. For the same reasons, the Court finds these cases are inapposite.

Plaintiffs nonetheless argue that the Court should follow Amgen, Inc. v. F. Hoffman-LaRoche Ltd., 456 F. Supp. 2d 267 (D. Mass. 2006) and find that Plaintiffs have alleged an "actual controversy." In Amgen, the defendant submitted a BLA to the FDA for approval to sell a new biologic. Prior to FDA approval, the plaintiff filed suit seeking a declaratory judgment that the defendant was currently infringing or will infringe the plaintiff's patents. The defendant moved to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim of current infringement and Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction. The court found that the plaintiff's allegation that the defendant was importing a drug into the United States which is materially indistinguishable from the plaintiff's patented invention was sufficient to state a claim for current infringement. Id. at 274. Further, relying on Glaxo, the court found that the immediacy requirement was satisfied for declaratory judgment jurisdiction where defendant completed several clinical trials, filed a BLA, constructed a manufacturing facility, and hired key personnel. Id. at 277–78. Notably, in making its immediacy finding, the court presumed that the FDA would approve the defendant's BLA. See id. at 278 ("An approval date that is 20 to 24 months away can be considered sufficiently imminent by this Court.").

The Court respectfully declines to follow Amgen because, for the reasons described supra, the Court finds that the Glaxo court's immediacy findings are inapposite where there is a BLA or an NDA rather than an ANDA or an aBLA, and where allegations assuming FDA approval are "speculative at best."[4] Juno Therapeutics, 2017 WL 2559735, at *3; see also Clarus

[4] In Glaxo, the Federal Circuit emphasized that finding "imminent FDA approval" for the ANDA submission was integral to its holding. See Glaxo, 110 F.3d at 1571 ("[D]eclaratory relief is available to the patentee asserting a 'method of making' claim if, as here, sufficient facts are alleged to create an actual case or controversy," which "may include, as here, imminent FDA approval . . . .").

Therapeutics, 2016 WL 5868065, at *3 (finding declaratory judgment complaint filed in connection with pending NDA was "based on speculative future events that lack immediacy"); Reckitt, 2014 WL 2119822, at *3 (finding declaratory judgment complaint filed in connection with pending NDA was "based on contingent future events" and "premature").

The Court may also consider allegations about Defendant's preparations to market and sell galcanezumab in determining whether infringement is sufficiently immediate. Here, there is no real doubt that Defendant intends to market galcanezumab if it receives FDA approval. [See, e.g., Teva I, Dkt. 21-2 at 18 (representing that galcanezumab has the potential to be a "first-in-class therap[y]" during May 24, 2016 presentation to investors)]. Plaintiffs have shown that Defendant has taken steps to execute this plan by hiring sales representatives to oversee the launch of galcanezumab. [Teva I, Dkt. No. 21 ¶ 21; Teva I, Dkt. No. 21-10; Teva II, Dkt. No. 10 ¶ 21; Teva II, Dkt. No. 10-13]. This, however, is insufficient to overcome the uncertainty over whether the FDA will ultimately approve galcanezumab.[5]

Therefore, the Court concludes that no controversy of sufficient immediacy and reality existed at the time that Plaintiffs filed their complaints to support declaratory judgment jurisdiction in the present cases. As such, the Court lacks jurisdiction to address Defendant's alternative argument for dismissal pursuant to Federal Rule of Civil Procedure 12(b)(6).[6]

[5] The Court finds that Plaintiffs' allegations about Defendant's Twitter account named @LillyMigraine and the website www.uncoveringmigraine.com are not indicative of an immediate and real controversy because the Twitter account and website do not discuss galcanezumab. [Teva I, Dkt. No. 21-8; Teva I, Dkt. No. 21-9].

[6] Plaintiffs request permission to take jurisdictional discovery in lieu of dismissal. [Teva I, Dkt. No. 26 at 13 n.10; Teva I, Dkt. No. 36 at 6 n.5; Teva II, Dkt. No. 10-11; Teva II, Dkt. No. 10-12]. A district court "retains broad discretion in determining whether to grant jurisdictional discovery." Maine Med. Ctr. v. United States, 675 F.3d 110, 118–19 (1st Cir. 2012) (quoting Blair v. City of Worcester, 522 F.3d 105, 110–11 (1st Cir. 2008)). The Court denies Plaintiffs' request because the Court finds that jurisdictional discovery would not change the fact that, at the

2. Discretion

Even if the Court were to find that an "actual controversy" exists, exercising jurisdiction in this case would conflict with the carefully calibrated regulatory scheme that Congress has established. In enacting the Safe Harbor provision of the Hatch-Waxman Act, Congress provided drug manufacturers with protection for activities related to seeking FDA approval to market new biologics. See supra at 7–8; Juno Therapeutics, 2017 WL 2559735, at *3. Moreover, unlike with ANDAs and aBLAs, Congress did not create a statutory scheme to facilitate infringement litigation prior to a biologic receiving FDA approval and entering the market. See supra at 6–7. To allow a declaratory judgment action to proceed where, as here, Plaintiffs acknowledge that the Defendant has not committed an act of infringement, is not currently infringing, and has only engaged in activities falling within the Safe Harbor provision, would allow Plaintiffs to circumvent the relevant Safe Harbor provision and the statutory framework. See Juno Therapeutics, 2017 WL 2559735, at *3 (finding that exercising declaratory judgment jurisdiction prior to FDA approval where defendant engaged only in activities protected by the Safe Harbor would conflict with the purpose of the Safe Harbor); Clarus Therapeutics, 2016 WL 5868065, at *4 (same); Amgen, Inc. v. Hoechst Marion Roussel, Inc., 3 F. Supp. 2d 104, 112–13 (D. Mass. 1998) (same).[7]

time Plaintiffs filed their complaints, FDA approval of galcanezumab was too uncertain to support a finding that a substantial controversy of sufficient immediacy and reality existed.

[7] Defendant argues that the Court should abstain from exercising declaratory judgment jurisdiction because Plaintiffs engaged in forum shopping. [Teva I, Dkt. No. 24 at 14–16]. The Court declines to reach the merits of this argument given the current record and its lack of jurisdiction.

III. CONCLUSION

For the foregoing reasons, Defendant's Motions to Dismiss [Teva I, Dkt. No. 23; Teva II, Dkt. No. 13] are GRANTED and the Amended Complaints are DISMISSED.

SO ORDERED.

September 27, 2018

/s/ Allison D. Burroughs
ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE